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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00D-0053, Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals.

Ladies and Gentlemen:

The American Hospital Association (AHA), representing nearly 5,000 hospitals, health networks and other providers of care, as well as more than 39,000 personal members, appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed guidance documents, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" and "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme." Our members have years of experience with reprocessing and reusing medical devices in the provision of safe, high quality care. We look forward to contributing our expertise to FDA's efforts and will work with the FDA as it considers its oversight of reused and reprocessed medical devices.

In particular, two of the AHA's personal membership groups and their members have been integral to assisting AHA in understanding the implications of these draft guidances for hospitals and in formulating these comments. The American Society for Healthcare Central Service Professionals (ASHCSP) has been a pioneer in developing safe and effective techniques for reprocessing devices; and its members have been proactively addressing the issues that form the basis for the FDA's proposed guidances for many years. The American Society for Healthcare Risk Management (ASHRM) is the preeminent professional society for healthcare risk management. The AHA is pleased to participate in this dialogue.

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"Truth in Labeling" for Devices Labeled as "Single Use Only"

In Section E.6. of the Enforcement Priorities guidance, FDA notes that further guidance may be issued on specific labeling for reprocessed devices. While this may be valuable, the AHA believes that the far greater concern is the lack of uniform standards for original equipment manufacturers (OEMs) that would make the "single use only" label meaningful and standardized.

For hospitals, reprocessing has had the historical benefit of allowing the treatment of a greater number of patients and the accrual of cost savings without sacrificing patient safety. The AHA believes that a balance can be struck that upholds the essential goal of safety, while minimizing regulatory burdens that might unnecessarily strain the resources of health care providers. The recent proliferation of costly "single use" devices (SUDs) and the demise of many reusable products has contributed to the strain on resources. The fact is that OEMs have very little incentive to label new devices as reusable. Doing so requires them to conduct extra testing and extends their legal liability. We understand the OEM's desire to control which products they place on the market and the warranties they offer. The "single use" labeling, however, is a misnomer.

The FDA does not require OEMs to justify the labeling of products as "single use." There are no standards in place to guide such labeling. This labeling is being used to place a limit on what an OEM warrants, i.e. that the device is safe and effective when used one time. Despite contrary public statements by organizations representing manufacturers and others, the "single use only" label in no way implies or asserts that legally or clinically there is a public health danger or any scientifically-based risk associated with using these devices more than once. In fact, as many years of hospital experience have repeatedly demonstrated, many of these devices labeled by OEMs as "single use only" can, with the application of appropriate reprocessing techniques, be safely and effectively used more than once.

In the October 1999 Proposed Strategy document, FDA indicated that it may require OEMs to provide, as part of the device's labeling, any information of which they are aware regarding the risks associated with reusing their SUDs. The AHA strongly supports such a revision. However, the FDA should go further. It should ensure that any labeling language which could imply a lack of safety or public health concern be backed by a body of scientific evidence setting out the quantifiable risk associated with the resterilization, reprocessing or reuse of each particular device.

Devices currently labeled as "single use only" and for which the OEM has already developed, or is aware of, safe and effective reprocessing techniques, should be required to change their labels to eliminate the "single use only" label, and the OEM should be required to add such reprocessing instructions to the labeling of the device. These instructions should indicate the number of times the device will perform without failure, as validated by the OEM. Thus, the FDA should consider a more objective and evidence-based approach to the labeling of these devices – in effect applying a "truth in labeling" concept to medical devices. For any devices

labeled as "single use only" and for which the OEM has no information or knowledge that reuse creates a safety or public health risk, the label should be removed.

The AHA recommends that FDA regulate the use of the "single use" label. The use of the "single use" label should be restricted to only those circumstances in which an OEM has demonstrated to the FDA that no resterilization, reprocessing, or reuse can safely occur. Such labeling must be premised upon a body of scientific evidence setting out the quantifiable risk associated with the resterilization, reprocessing or reuse of the particular device. Further, it is critical that the FDA require the same level of scientific rigor from OEMs, regardless of whether the device is to be labeled as "single use" or reusable

Exclusion of Opened-But-Unused Items

It is not uncommon in hospitals that a sterile SUD is opened in preparation for a medical procedure but, for a variety of reasons, is not subsequently used. Typically these devices are resterilized and repackaged at the hospital. Another typical scenario occurs in the context of assembling customized procedure trays. Sterile processing professionals assemble, wrap and sterilize these trays, which may consist of many single-use and disposable items. It is essential that health care facilities be permitted to continue to conduct these activities without subjecting this activity to a burdensome and unnecessary regulation.

We are pleased that FDA has recognized that this practice does not provide a public safety concern and has excluded it from further regulation. We are aware of no scientific evidence that would establish a public health risk associated with the resterilization and repackaging of "opened but unused" SUDs. Since they have not, by definition, been previously used on a patient, the reprocessing of these devices poses no risk of patient-to-patient infection. Further, hospitals have many years of experience in sterilization and resterilization processes as these are routinely performed on many types of medical devices.

Existing regulation at 21 CFR 801.4, under the General Labeling Provisions, currently requires that if a manufacturer knows that his device is to be used for conditions, purposes, or uses other than the ones for which he offers the device, he is required to provide adequate labeling for such a device which accords with such other uses. An example of such a "use" would be the resterilization and repackaging of devices that are frequently "open-but-unused." While original equipment manufacturers (OEMs) sometimes provide resterilization instructions for device users, this is by no means a common practice. The AHA is collecting examples of such lapses in labeling and will be sharing this list of devices and their brands with FDA soon.

The AHA urges FDA to enforce the requirements under 21 CFR 801.4 and require OEMs to provide special sterilization instructions for devices that are frequently "open-but-unused."

Health Care Facilities and Existing Oversight Authority

As discussed later in this letter, the AHA questions whether FDA has the authority to regulate reprocessing performed at hospitals. Putting this issue aside for the moment, the AHA believes that in formulating its enforcement strategy, the FDA must consider the existing high level of internal and external oversight to which hospitals are already subject, which impacts upon the safety and effectiveness of the reprocessing activities in which hospitals engage. Despite the AHA's previous statements in this regard, FDA has failed to address this issue and instead sets out to regulate hospitals in exactly the same manner as it has regulated OEMs when, in fact, there are significant differences between the two that should be factored into FDA's consideration of an enforcement strategy.

Health care facilities are subject to significant regulatory and accreditation oversight by entities such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), the Health Care Financing Administration (HCFA), state licensing authorities, and other county and city agencies, particularly as with respect to patient safety and quality of care. By contrast, manufacturers have no existing source of outside regulation beyond FDA. And while the FDA recognized in its November 1999 Proposed Strategy that a decision to regulate health care facilities may require collaboration with "accredited third-party organizations or other federal agencies," we were disappointed that the Enforcement Priorities guidance failed to further develop this concept.

Hospitals are, fundamentally, providers of medical care and services. Hospitals and physicians are integrally related in the delivery of care within the institution. Physicians are medical directors of an institution, department heads, and essential to the variety of quality improvement and quality assurance activities. With respect to reprocessing activities, if is our understanding that the institution's medical director, at a minimum, is involved. For certain devices, department heads, on behalf of practicing physicians are also directly involved. Often the reprocessing activities of hospitals are overseen by a multi-disciplinary committee, consisting of clinical and operational staff. This committee, which is authorized by the medical staff, typically monitors reprocessing quality assurance and improvement activities, recommends strategies for improving performance, and reports such findings and recommendations to the facility's performance improvement oversight committee, medical staff, and governing body. Through its membership, activities, and reporting structure, this multi-disciplinary committee meets the requirements of numerous JCAHO standards, including those in the chapters on Surveillance, Prevention and Control of Infection, Leadership, Improving Organization Performance, and Governance. Existing non-FDA regulatory oversight, which the AHA believes includes the components necessary to address and satisfy many of the FDA's concerns in this area, has resulted in the development of these processes.

Again, AHA reiterates that in any effort to develop regulatory guidance that applies to a hospital, the FDA must consider the high level of external regulatory and other oversight and internal controls to which health care facilities are already subject.

Enforcement Discretion

The FDA has proposed, through its use of enforcement discretion, that hospital and third party reprocessors of SUDs be excused from compliance with premarket requirements for reprocessed SUDs for a period of time that varies with the categorization of the reprocessed device as high, moderate, or low risk according to the Review Prioritization Scheme (RPS). In addition, the FDA would provide hospitals with six months of enforcement discretion for compliance with other non-premarket requirements such as registration, listing, and Quality Systems regulations. The AHA has concerns and questions regarding this enforcement discretion.

When the FDA exercises its enforcement discretion with regard to an activity in which an entity engages, the agency is effectively making a decision that there is no real threat to the public health and safety related to this activity and that such an activity may continue. We are concerned that the draft guidance fails to make clear for the public, health care facilities, and other regulators who rely on the FDA's expertise in this area, that it is the FDA's judgment during periods of enforcement discretion that reprocessing and reuse of such devices is acceptable from a regulatory and compliance standpoint. It is important that there be clarity about the FDA's views on issues of safety and efficacy. Such clarification from FDA should apply to the agency's current use of enforcement discretion as well as to its future application of enforcement discretion as proposed in this draft guidance.

FDA's statement over time demonstrate that it does not believe reprocessing presents a risk to public health or safety. For instance, in the October 6, 1999 letter from David Feigal, MD, MPH, the Director of the Center for Devices and Radiological Health, to Larry Pilot, Esq. of McKenna & Cuneo, denying the Medical Device Manufacturer Association's Citizen's Petition to ban reprocessing, Dr. Feigal stated that, "In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source." One year earlier, the FDA denied a similar citizen's petition from the Health Industry Manufacturer's Association, citing, among other things, a lack of evidence of adverse outcomes. At that time, the FDA specifically encouraged "trade and scientific organizations, OEMs, user facilities, and others to provide any data demonstrating adverse patient outcomes from the use of reprocessed 'single use only' devices," but noted that as of that time, FDA had seen "no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes." (Letter to Nancy Singer, Esq., July 13, 1998.) And most recently, in his testimony before the Subcommittee on Oversight and Investigations, House Committee on Commerce on February 10, 2000, Dr. Feigal stated that in a review of the Medical Device Reporting reports received by Center for Devices and Radiological

Health over the past three years, "we can discern no pattern of failures with reused SUDs that differs from patterns observed with the initial use of SUDs."

After many years of experience with reprocessed SUDs and despite a significant period of study and specific requests from FDA and others to be informed of the details relating to problems with reprocessed SUDs, the health care field has not yet seen any reliable evidence of a problem. **Therefore, the AHA urges FDA to include the following language in section D of its final enforcement priorities document: "To date, FDA has used its enforcement discretion not to enforce premarket review requirements against third party reprocessors -- and will continue to use the same enforcement discretion to 'phase in' the enforcement of premarket review requirements against hospital and third party reprocessors -- in part because the FDA has not found sufficient evidence to suggest that reprocessing presents a threat to public health and safety."**

In addition, the AHA is concerned that the discussion in Sections D and F of the draft Enforcement Priorities guidance contains conflicting periods of time for such enforcement discretion. For instance, in Section D, FDA states that it will "begin to enforce premarket notification and premarket application requirements" within six months of a final guidance for a high risk device, within 12 months for a moderate risk device, and within 18 months for a low risk device. By contrast, Section F.1. states that FDA intends to continue to exercise its enforcement discretion for premarket requirements for one year for high risk devices, 18 months for moderate risk devices and two years for low risk devices. While AHA understands that this difference in timing can be explained by including the six-month period that FDA reserves to review and act on the premarket submission, it is critical that it be clear exactly how much time hospitals have to come into compliance with the premarket requirements. The way in which the guidance currently reads is confusing and should be clarified. **We urge FDA to clarify that the timeframe described in Section F.1., which includes both the time for a hospital to prepare and send a premarket submission to the FDA and the time for FDA to process and act on such submission, be stated as the period for which FDA will continue to exercise its enforcement discretion.**

Review Prioritization Scheme

In general, the AHA believes that the FDA's risk-based categorization scheme addresses the right issues. Factors such as risk of infection and device performance are critical in determining whether or not reprocessing is appropriate, safe and effective. However, because many of the questions posed in the proposed risk prioritization scheme are subjective in nature, we are concerned that some of the classifications may have been inconsistently applied. The public must have confidence that the categorizations rendered by the scheme are well-grounded in science rather than on speculation.

Therefore, we strongly urge that FDA make the entire risk-based categorization process transparent and public. That is, all the responses to the questions posed in the flowcharts, as well as all supporting documentation used in establishing a risk categorization for a particular type of device, should be publicly released and easily accessible. In addition, AHA believes that in determining the final list of frequently reprocessed SUDs and their risk category, the FDA should work with a panel of professionals from multiple disciplines. In this way, representatives from multiple disciplines, including clinicians, sterile processing professionals, and manufacturers could provide FDA with a forum to discuss all available evidence regarding the safety of reprocessing SUDs and, with the benefit of their expert knowledge and experience, develop the most appropriate categorization of devices.

FDA's Statutory Authority over Hospital-Based Reprocessing

In Sections E and F of the Enforcement Priorities document, FDA asserts that hospital reprocessing can be subject to the Act's premarket and other regulatory requirements. The AHA seeks clarification about the FDA's authority to regulate hospital reprocessing activities. Further, even assuming statutory authority, we believe that the precedent-setting imposition of FDA manufacturing regulations on hospital reprocessing through a guidance document rather than through a formal rulemaking process is inconsistent with the requirements of the Administrative Procedures Act (APA).

The FDA's assertion of regulatory authority is apparently based on the premise that reprocessing is the legal equivalent of manufacturing. Under the current statutory and regulatory scheme, the FDA is charged with regulating the design, manufacture and commercial sale of medical devices. However, the AHA has not found a FDA statutory provision nor any regulation that specifically addresses the issue of reprocessing a single-use medical device for subsequent reuse.

Reprocessing neither affects a device that is in the process of being delivered in an interstate commercial transaction nor results in a new product that is made available in interstate commerce. This brings into question the FDA's jurisdiction over reprocessing activities. In particular, for hospital-based reprocessing of devices, the device has already reached its final user, the physician, and is no longer in interstate commerce. When a product no longer remains in interstate commerce the authority of the FDA to regulate ceases.

The FDA recognized as much when it established its policy with respect to reprocessing by health care facilities, as expressed in Compliance Policy Guide (CPG) 300.500, which, for over 20 years, has placed responsibility for hospitals' reprocessing and reuse of SUDs with the hospitals, without any FDA oversight or affirmative regulatory requirements

Even assuming that FDA does have statutory authority to regulate hospital reprocessing activities, we believe that the FDA has not followed the requirements of the Administrative

Procedure Act (APA) which are necessary for the promulgation of legally binding regulations or rules. 5 USC 551 (4) defines "rule" as part of an "agency statement ... designed to implement ... law ...or describing practice requirements of an agency." 5 USC 551(5) defines "rule making" as "agency process for formulating, amending or repealing a rule." 5 USC 553 sets forth the procedure that must be followed by an agency undergoing rule making, which must include notice, statement of legal authority and the terms of the proposed rule. If the agency is issuing interpretative rules, general statements of policy or rules of agency organization, procedure, or practice, the procedures required by the APA do not apply.

In the case of the Enforcement Priorities guidance, the FDA is asserting that it has always had the authority to regulate reprocessing. Even assuming such jurisdiction, the Enforcement Priorities guidance is clearly much more than just interpretive rules or a general statement of policy. It is in fact an entirely new application of FDA regulations to hospital-based reprocessing. The Enforcement Priorities guidance imposes substantial and immediate burdens on hospitals, and violations could result in serious civil and criminal penalties and damage to reputations. This being the case, the guidance is regulation, and the FDA has not engaged in rulemaking in its promulgation.

Given this proposed precedent-setting expansion of FDA's regulatory authority into hospital reprocessing activities, FDA should suspend issuance of guidance and, to the extent it intends to assert jurisdiction to regulate hospital reprocessing activities, proceed with a formal rulemaking process in accordance with the APA. Such a rulemaking process affords the public, in this case our member hospitals, with all rights and remedies that apply when a regulation is promulgated.

In the event that such a rulemaking is undertaken, we recommend that FDA address within it a number of issues of concern to the AHA:

- It is critical that any additional regulation be inclusive of all health care facilities and other providers who engage in reprocessing activities. This would include physician offices, group practices, ambulatory surgical centers, and any other facility that reprocesses SUDs.

- Under current circumstances, a hospital would be unable to assert "substantial equivalence" with a predicate device, and hence could not submit complete premarket notifications (510(k)), because it would not have access to design specifications that are currently considered proprietary by OEMs. In the absence of FDA's requiring OEMs to share this data, the practical impact would be that hospital reprocessing would cease. Therefore, the FDA should specifically address OEM obligations to share design specifications with reprocessors or, alternatively, exempt reprocessed devices from premarket requirements.

- Reporting requirements should be non-duplicative. The AHA is concerned that subjecting hospitals to both the manufacturer and user facility device reporting requirements would be redundant and an inefficient use of resources.

Again, the AHA appreciates the opportunity to comment and to participate in the dialogue among the FDA and interested stakeholders. If you have questions regarding these comments, feel free to call me, Carmela Coyle, senior vice president for policy, at (202) 626-2266, or Roslyne Schulman, senior associate director for policy development, at (202) 626-2273.

Sincerely,

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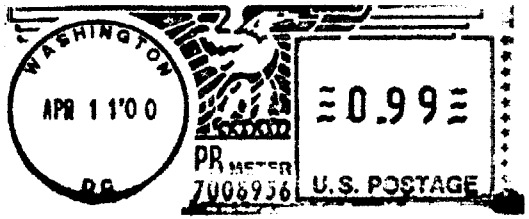

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